

REMARKS

Claims 3-14, 18, 20-25 are pending. Claims 24-25 have been newly added. Claims 15-17 have been canceled without prejudice or disclaimer as to the underlying subject matter. Claims 3-14, 18, and 20-23 have been amended without prejudice or disclaimer to clarify the claimed subject matter. Support for the new and amended claims can be found throughout the Specification and claims as originally filed, for example, at page 13, lines 24 - 28 and page 18, lines 6-19. No new matter enters by way of the foregoing amendment.

At the outset, Applicants would like to thank the Examiner for withdrawing the rejections under 35 U.S.C. § 112, second paragraph.

I. Amendment to the Specification

Applicants have amended the Specification in accordance with the Office's suggestion. Final Office Action at page 5. Specifically, consistent with the Examiner's suggestions, Applicants have inserted SEQ ID NO: 1 into the paragraph starting on page 43, line 25 of the Specification. As such, Applicants respectfully request withdrawal of the objection.

II. Rejection under 35 U.S.C. § 112, First Paragraph, Written Description

Claims 3-14 and 20-23 have been rejected under 35 U.S.C. §112, first paragraph, as allegedly containing subject matter which was not described in the specification in such a way as to reasonably convey to one of skill in the art that the inventors, at the time the application was filed, had possession of the claimed invention. Final Office Action at page 3. Applicants respectfully disagree and traverse the rejection.

Applicants assert that the purpose of the written description requirement is to ensure that the inventors had possession of the claimed subject matter, *i.e.*, to ensure that the inventors actually invented what is claimed. *Gentry Gallery Inc. v. Berkline Corp.*, 134 F.3d 1473, 1479, 45 U.S.P.Q.2d 1498, 1503 (Fed. Cir. 1998); *Lockwood v. American Airlines*, 107 F.3d 1565, 1572, 41 U.S.P.Q.2d 1961, 1966 (Fed. Cir. 1997); *In re Alton*, 76 F.3d 1168, 1172, 37 U.S.P.Q.2d 1578, 1581 (Fed. Cir. 1996). A related and equally well-established principle of patent law is that claims "may be broader than the specific embodiment disclosed in a specification." *Ralston Purina Co. v. Far-mor-Co*, 772 F.2d 1570, 1575, 227 U.S.P.Q. 177, 179

(Fed. Cir. 1985), *quoting In re Rasmussen*, 650 F.2d 1212, 1215, 211 U.S.P.Q. 323, 326 (C.C.P.A. 1981).

At the outset, Applicants would like to thank the Examiner for indicating that the specification “describes a soybean plant that is transformed with SEQ ID NO: 1, which is identified as the FAD2-1A intron, operably linked to a heterologous promoter in sense or anti-sense orientation, wherein the plant produces seed with more oleic acid than a plant with similar background but lacking said nucleic acid, including oleic levels of about 30% to 60% with one example of an oleic acid level of 80%.” Final Office Action at pages 3-4. Indeed, given the teachings of at least the Specification, one of skill in the art would readily recognize that Applicants were in possession of the invention at the time of filing.

Applicants disagree with the Examiner’s assertion that the claims do not satisfy the written description requirement because “the specification only describes one specific sequence transformed into a soybean plant, wherein the soybean plant has increased oleic acid in the seed.” Final Office Action at page 4. The Examiner goes on to assert that “[t]he specification does not describe any other sequences that have at least 95% or greater identity to at least 100 contiguous nucleotides of SEQ ID NO: 1 in a soybean plant having more oleic acid in the plant seed than in seeds of a similar plant that is not transformed with the same sequence.” *Id.* Applicants disagree.

The Examiner’s conclusion regarding written description lacks a basis. For one, Applicants are not required to describe every possible sequence that is transformed into a soybean plant which is capable of increasing oleic acid content in a seed as the Examiner suggests. Further, examples covering every facet of the invention are not required in order to satisfy the written description requirement under 35 U.S.C. §112, first paragraph. *Faulkner v. Inglis*, 448 F.3d 1357, 1363, 79 U.S.P.Q.2d 1001, 1007 (Fed. Cir. 2006). Irrespective of this, Applicants are not claiming transformed soybean plants with any possible nucleic acid sequence. Rather, the claims recite SEQ ID NO: 1, and this sequence is aptly described by the specification. However, the Examiner ignores this in rejecting the claims.

Moreover, Applicants have described representative soybean plants transformed with SEQ ID NO: 1 in the Examples and elsewhere in the specification. The Specification also provides descriptions of the components of recombinant constructs, methods of constructing

such constructs, and exemplary constructs used to transform cells plants. Specification, for example, at page 41, line 21 - page 57, line 17. For example, soybean plants transformed with a pCGN5469 construct are capable of producing seeds with more oleic acid than soybean plants having a similar genetic background but lacking a nucleic acid molecule comprising SEQ ID NO: 1. As described in Table I, all eight fatty acid composition data points isolated from soybean lines transformed with a pCGN5469 construct exhibit more oleic acid than plants having a similar genetic background but lacking a nucleic acid molecule comprising at least 100 contiguous nucleotides of SEQ ID NO: 1. Furthermore, pCGN5471 provides another example of a construct comprising at least 100 contiguous nucleotides of SEQ ID NO: 1. Specification, for example, at Figure 3. Soybean plants transformed with a pCGN5471 construct are capable of producing seeds with more oleic acid than soybean plants having a similar genetic background but lacking a nucleic acid molecule comprising at least 100 contiguous nucleotides of SEQ ID NO: 1. As described in Table I, all six fatty acid composition data points, isolated from soybean lines transformed with a pCGN5471 construct, exhibit more oleic acid than soybean plants having a similar genetic background but lacking a nucleic acid molecule comprising at least 100 contiguous nucleotides of SEQ ID NO: 1. However, in rejecting the claims, the Office improperly ignores this point.

For the foregoing reasons, Applicants submit that one of ordinary skill in the art would recognize that at the time of filing Applicants were in possession of the claimed invention. Therefore Applicants respectfully request that the written description rejection under 35 U.S.C. §112, first paragraph, be withdrawn.

III. Rejection under 35 U.S.C. § 112, First Paragraph, Enablement

Claims 3-14, 20 and 23 stand rejected under 35 U.S.C. § 112, first paragraph, as allegedly containing subject matter which was not described in the Specification in such a way so as to enable those skilled in the art to make and/or use the invention commensurate in scope with the claims. Office Action at page 4. Applicants disagree.

In rejecting the claims, the Examiner asks for clarification regarding Table I and asserts that “the specification is unclear in reciting the numbers ‘5469’ and ‘5471’ in Table I without any statement that these numbers referred to soybean plants transformed with pCGN5469 or

pCGN5471.” Final Office Action at page 5. The Examiner also asserts that “the specification is also unclear at the first line of page 44, where it refers to a ‘FAD2-1A intron’ without a sequence identifier, wherein the ‘FAD2-1A’ intron is cloned into pCGN3892, then into pCGN9372 and then into pCGN5469 and pCGN5471.” *Id.* As a remedy, the Examiner suggests that “[i]f the FAD2-1A sequence that is cloned into pCGN3892 is SEQ ID NO: 1, then the specification should be amended to recite ‘SEQ ID NO: 1’ after the recitation of FAD2-1A in the first line of page 44.” *Id.* Applicants disagree with the Examiner’s assertion that Table I is unclear, but have amended the Specification in a manner that is consistent with the Examiner’s suggestion solely in order to facilitate prosecution.

Applicants continue to disagree with the Examiner’s assertion that the claims are not enabled because there is a high level of unpredictability in the art. *Id.* at page 5. Again, the Specification provides for numerous soybean plants capable of producing soybean seeds with fatty acid compositions within levels of the claimed invention. Specification, for example, at Table I. Several of these soybean plants are transformed with constructs comprising at least 100 contiguous nucleotides of SEQ ID NO: 1. Specification, for example, at page 43, line 23 - page 44, line 6; and Figure 2. For instance, soybean plants transformed with a pCGN5469 construct as well soybean plants transformed with a pCGN5471 construct are capable of producing seeds with more oleic acid than plants having a similar genetic background but lacking a nucleic acid molecule comprising at least 100 contiguous nucleotides of SEQ ID NO: 1. As described in Table I, all 8 fatty acid composition data points isolated from soybean lines transformed with a pCGN5469 construct exhibit more oleic acid than plants having a similar genetic background but lacking a nucleic acid molecule comprising at least 100 contiguous nucleotides of SEQ ID NO: 1. Further, as described in Table I, all 6 fatty acid composition data points isolated from soybean lines transformed with a pCGN5471 construct exhibit more oleic acid than plants having a similar genetic background but lacking a nucleic acid molecule comprising at least 100 contiguous nucleotides of SEQ ID NO: 1. However, in rejecting the claims, the Office improperly ignores this point. Together, Table I describes 14 fatty acid composition data points isolated from soybean lines independently transformed with pCGN5469 or pCGN5471 constructs. All 14 of these fatty acid composition data points exhibit more oleic acid than plants having a similar genetic background but lacking a nucleic acid molecule comprising at least 100

contiguous nucleotides of SEQ ID NO: 1. Alone, this is enough to overcome the Examiner's enablement rejection.

In rejecting the claims, the Office asserts that "the specification fails to provide examples or guidance with regard to choosing from the large number of soybean plants transformed with any of the vast number of nucleotide sequences." *Id.* at page 6. Applicant disagrees. As described above, the Specification provides for numerous constructs and transformed plants capable of producing soybean seeds with fatty acid compositions within levels of the claimed invention. Specification, for example, at Figures 2-3 and Table I. Moreover, Tables I - III provide fatty acid composition data such that one of skill in the art would have the ability to choose transformed plants with a desired fatty acid profile without undue experimentation.

Further, post-filed co-pending application U.S. Application Serial No. 11/376,328 confirms that soybean plants transformed with at least 100 contiguous nucleotides of SEQ ID NO: 1 are capable of producing seeds with more oleic acid than soybean plants having a similar genetic background but lacking at least 100 contiguous nucleotides of SEQ ID NO: 1. See, for example, U.S. Application Serial No. 11/376,328 Specification at Tables 8-20; 25; and 26. For example, as described in U.S. Application Serial No. 11/376,328, at least the following constructs are capable of producing seeds with more oleic acid than soybean plants having a similar genetic background but lacking at least 100 contiguous nucleotides of SEQ ID NO: 1: pMON97555 includes a 100 nucleotide portion of SEQ ID NO: 1, pMON93771 includes a 120 nucleotide portion of SEQ ID NO: 1, pMON97554 includes a 160 nucleotide portion of SEQ ID NO: 1, pMON93770 includes a 180 nucleotide portion of SEQ ID NO: 1, pMON93759 includes a 180 nucleotide portion of SEQ ID NO: 1, pMON97553 includes a 220 nucleotide portion of SEQ ID NO: 1, pMON93758 includes a 260 nucleotide portion of SEQ ID NO: 1, pMON97552 includes a 280 nucleotide portion of SEQ ID NO: 1, pMON95829 includes a 320 nucleotide portion of SEQ ID NO: 1, pMON97562 includes a 320 nucleotide portion of SEQ ID NO: 1, pMON97563 includes a 320 nucleotide portion of SEQ ID NO: 1, *FAD2-1A* intron, pMON93505 includes a 320 nucleotide portion of SEQ ID NO: 1, pMON93506 includes a 320 nucleotide portion of SEQ ID NO: 1, and pMON93501 includes 420 nucleotides of SEQ ID NO:

1.¹ Given this, one of skill in the art at the time the invention was made would have the ability to practice the claimed invention in a manner that is commensurate in scope with the claims without undue experimentation.

Moreover, given the teachings of the Specification, one of skill in the art would have the ability to make nucleotide substitutions to SEQ ID NO: 1 without undue experimentation. Performing routine and well-known steps cannot create undue experimentation even if it is laborious. *See In re Angstadt*, 537 F.2d 498, 504, 190 U.S.P.Q. 214, 218-219 (C.C.P.A. 1976). That is, one of skill in the art would have the ability to transform a soybean plant with a nucleic acid molecule comprising a polynucleotide having at least 95% identity to at least 100 nucleotides of SEQ ID NO: 1 with the expectation that seeds isolated from those plants would have higher oleic acid than soybean plants having a similar genetic background but lacking a nucleic acid molecule comprising SEQ ID NO: 1. However, the Examiner disregards this when maintaining the rejections over the claims.

Given the disclosure, Applicant respectfully submits that one of ordinary skill in the art would have the requisite skill to create a plant transformed with a nucleic acid molecule comprising at least 100 contiguous nucleotides of SEQ ID NO: 1, wherein the transformed plant is capable of producing seeds with more oleic acid than plants having a similar genetic background but lacking a nucleic acid molecule comprising at least 100 contiguous nucleotides of SEQ ID NO: 1. Applicant has sufficiently described the claimed invention such that one of skill in the art in light of the specification would be able to practice the invention commensurate in scope with the claims. In sum, such disclosure provides adequate direction, including working examples, to teach the skilled artisan how to make and use the claimed invention without undue experimentation.

Accordingly, for at least these reasons, it is submitted that the claims are sufficiently enabled under 35 U.S.C. § 112, first paragraph, and withdrawal of this rejection is respectfully requested.

¹ SEQ ID NO: 1 is 420 nucleotides in length.

CONCLUSION

In view of the above, each of the presently pending claims is believed to be in immediate condition for allowance. Accordingly, the Examiner is respectfully requested to withdraw the outstanding objection and rejections of the claims, and to pass this application to issue. The Examiner is encouraged to contact the undersigned at (202) 942-5186 should any additional information be necessary for allowance.

Respectfully submitted,

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